

5

PATENT  
ATTORNEY DOCKET NO. 44921-5029-01-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

William E. MUNGER *et al.*

Application No.: 09/960,706

Filed: September 24, 2001

For: IDENTIFYING DRUGS FOR AND  
DIAGNOSIS OF BENIGN PROSTATIC  
HYPERPLASIA USING GENE  
EXPRESSION PROFILES

Group Art Unit: 1645

Examiner: Unassigned

Commissioner for Patents  
Washington, D.C. 20231

Sir:

**PRELIMINARY AMENDMENT**

**IN THE CLAIMS:**

Please amend claims 1, 6, 7, 22, 28, 47 and 48 as follows:

1.(amended) A method of screening for or identifying an agent that modulates the onset or progression of benign prostatic hyperplasia (BPH), comprising:

- (a) preparing a first gene expression profile of BPH cells or BPH-like cell population;
- (b) exposing the cells to the agent;
- (c) preparing a second gene expression profile of the agent exposed cells; and
- (d) comparing the first and second gene expression profiles.

6.(amended) The method of claim 1, wherein the BPH cell is selected from the group consisting of prostate cells from a BPH patient, a cell line in Table 7 and a derivative thereof.

7.(amended) The method of claim 2, wherein the expression levels are for two or more genes.

22.(amended) The set of oligonucleotide probes of claim 18, wherein the probes are attached to a solid support.

28.(amended) The solid support of claim 24, wherein the solid support is an array comprising at least 10 different oligonucleotides in discrete locations per square centimeter.

47.(amended) The method of claim 45, wherein the expression levels are for two or more genes.

48.(amended) The method of claim 1, wherein the gene expression profile is detected by a branched DNA (bDNA) method.

Please add the following new claims 51-54:

51.(new) The method of claim 8, wherein the gene expression level is detected by a branched DNA (bDNA) method.

52.(new) The method of claim 12, wherein the gene expression level is detected by a branched DNA (bDNA) method.

53.(new) The method of claim 38, wherein the gene expression level is detected by a branched DNA (bDNA) method.

54.(new) The method of claim 43, wherein the gene expression level is detected by a branched DNA (bDNA) method.

**REMARKS**

The above amendments to the claims do not represent any surrender of the subject matter of the claims as originally filed. A marked-up copy of the amended claims showing the changes has been attached hereto as the "APPENDIX." Claim 1 has been amended solely to correct minor typographical errors. The amendments to claims 6, 7, 22, 28, 47 and 48 have been made solely to remove multiple dependency from the claim set in order to reduce filing fees. New claims 51-54 have full support in claim 48 as originally filed. It is respectfully submitted that no prohibited new matter has been introduced by the amendments.

**Except** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a constructive petition for extension of time in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,  
MORGAN, LEWIS & BOCKIUS LLP

June 11, 2002

*Robert Smyth for Michael S. Tuscan, Ph.D.*  
Michael S. Tuscan, Ph.D. RN 50801  
Registration No. 43,210

Customer No. 09629  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue  
Washington, DC 20004  
(202) 739-3000  
(202) 739-3001 – fax

**APPENDIX**  
**Marked-Up Copy of the Amended Claims**  
KEY: [deleted text]; new text

1.(amended) A method of screening for or identifying an agent that modulates the onset or progression of benign prostatic hyperplasia (BPH), comprising:

- (a) preparing a first gene expression profile of BPH cells or BPH-like cell population;
- (b) exposing the cells to the agent;
- (c) preparing a second gene expression profile of the agent exposed cells[-]; and
- (d) comparing the first and second gene expression profiles.

6.(amended) [A] **The** method of [any one of claims] claim 1[-5], wherein the BPH cell is selected from the group consisting of prostate cells from a BPH patient, a cell line in Table 7 and a derivative thereof.

7.(amended) [A] **The** method of [any one of claims] claim 2[-5] , wherein the expression levels are for two or more genes[-].

22.(amended) [A] **The** set of oligonucleotide probes of [any one of claims] claim 18[-24], wherein the probes are attached to a solid support.

28.(amended) [A] **The** solid support of [any one of claims] claim 24[-27], wherein the solid support is an array comprising at least 10 different oligonucleotides in discrete locations per square centimeter.

47.(amended) [A] **The** method of claim 45 [or 46], wherein the expression levels are for two or more genes.

48.(amended) [A] **The** method of [any one of claims] claim 1[-8, 12, 38 or 43], wherein the gene expression profile [or gene expression level] is detected by a branched DNA (bDNA) method.